

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): DAVID MEEKER, ET AL.

Group Art Unit: TBA

Serial No.: 09/884,526

Examiner: TBA

Filed: June 19, 2001

For: COMBINATION ENZYME REPLACEMENT, GENE THERAPY AND
SMALL MOLECULE THERAPY FOR LYSOSOMAL STORAGE DISEASES

RESPONSE TO "NOTICE TO FILE MISSING PARTS"

Commissioner for Patents
Washington, D.C. 20231

Sir:

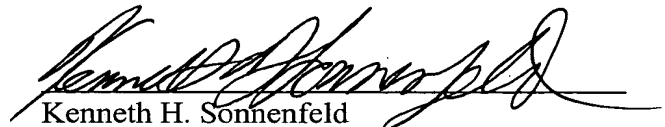
In response to the NOTICE TO FILE MISSING PARTS OF APPLICATION--
FILING DATE GRANTED dated June 19, 2001, Applicant(s) submit(s) herewith the
following documents for appropriate action by the U.S. Patent and Trademark Office:

- ☒ Copy of Notice to File Missing Parts
- ☒ Executed Declaration
- ☒ Application Filing Fees (Check \$130.00)
- ☒ Petition And Fee For Extension of Time (37 C.F.R. §1.136(a))
- ☒ Petition Filing Fees (Check \$110.00)
- ☐ Please charge the required fee of \$ _____ to deposit account no. 13-4500, Order No. _____.
- ☒ The Commissioner is hereby authorized to charge any additional fees which may be
required by this paper, or credit any overpayment to Deposit Account No. 13-4500,
Order No. 4274-4000. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,
MORGAN & FINNEGAN, L.L.P.

Dated: December 13, 2001

By:


Kenneth H. Sonnenfeld

Registration No. 33,285

Correspondence Address:

MORGAN & FINNEGAN, L.L.P.
345 Park Avenue
New York, NY 10154-0053
(212) 758-4800 Telephone
(212) 751-6849 Facsimile

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): DAVID MEEKER, ET AL.

Group Art Unit: TBA

Serial No.: 09/884,526

Examiner: TBA

Filed: June 19, 2001

For: COMBINATION ENZYME REPLACEMENT, GENE THERAPY AND SMALL
MOLECULE THERAPY FOR LYSOSOMAL STORAGE DISEASES

TRANSMITTAL OF DECLARATION PURSUANT TO 37 C.F.R. §1.63

Commissioner for Patents
Washington, D.C. 20231

Sir:

Transmitted herewith is a declaration pursuant to 37 C.F.R. §1.63 for the above-identified application.

The surcharge, pursuant to 37 C.F.R. §1.16(e), for filing a declaration on a date later than the filing date of the application is as follows:

- ☒ Filing by other than a small entity (\$130)
- ☐ Filing by a small entity (\$65)
- ☒ A check in the amount of \$130.00 to cover the surcharge fee is enclosed.
- ☐ Charge surcharge fee to Deposit Account No. 13-4500, Order No. _____. A
DUPLICATE COPY OF THIS SHEET IS ATTACHED.
- ☒ The Commissioner is hereby authorized to charge any additional fees which
may be required for filing this paper, or credit any overpayment to Deposit
Account No. 13-4500, Order No. 4274-4000. A DUPLICATE COPY OF
THIS SHEET IS ATTACHED.

Respectfully submitted,
MORGAN & FINNEGAN, L.L.P.

Dated: December 13, 2001

By:


Kenneth H. Sonnenfeld
Registration No. 33,285

Correspondence Address:

MORGAN & FINNEGAN, L.L.P.
345 Park Avenue
New York, NY 10154-0053
(212) 758-4800 Telephone
(212) 751-6849 Facsimile



12-19-01

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Docket No. 4274-4000

#4

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): DAVID MEEKER, ET AL.

Group Art Unit: TBA

Serial No.: 09/884,526

Examiner: TBA

Filed: June 19, 2001

For: COMBINATION ENZYME REPLACEMENT, GENE THERAPY AND
SMALL MOLECULE THERAPY FOR LYSOSOMAL STORAGE DISEASES

EXPRESS MAIL CERTIFICATE

Express Mail Label No.: EF308383445US

Date of Deposit: DECEMBER 13, 2001

I hereby certify that the following attached paper(s) and/or fee

1. PETITION REQUESTING CORRECTION OF FILING RECEIPT & ENCLOSURES
2. TRANSMITTAL OF DECLARATION PURSUANT TO 37 C.F.R. §1.63
3. CHECK \$130.00
4. COMBINED DECLARATION AND POWER OF ATTORNEY (Executed)
5. Part 2 – COPY OF NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION
6. RESPONSE TO "NOTICE TO FILE MISSING PARTS"
7. PETITION AND FEE FOR EXTENSION OF TIME (37 C.F.R. §1.136(a))
8. CHECK \$110.00
9. RETURN RECEIPT POSTCARD

are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. §1.10 on the date indicated above and is addressed to the Commissioner for Patents, Washington, D. C. 20231.

Jesus Raul Remedios

(Typed or printed name of person mailing papers(s) and/or fee)

(Signature of person mailing paper(s) and/or fee)

Correspondence Address:

MORGAN & FINNEGAN, L.L.P.
345 Park Avenue
New York, NY 10154-0053
(212) 758-4800 Telephone
(212) 751-6849 Facsimile

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UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

| APPLICATION NUMBER | FILING/RECEIPT DATE | FIRST NAMED APPLICANT | ATTORNEY DOCKET NUMBER |
|--------------------|---------------------|-----------------------|------------------------|
| 09/884,526 | 06/20/2001 | David Meeker | 4274-4000 |

CONFIRMATION NO. 2532

FORMALITIES LETTER



OC00000006418070

MORGAN & FINNEGAN, L.L.P.
345 Park Avenue
New York, NY 10154-0053

Date Mailed: 08/13/2001

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The oath or declaration is unsigned.
- To avoid abandonment, a late filing fee or oath or declaration surcharge as set forth in 37 CFR 1.16(e) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.
- The balance due by applicant is \$ 130.

*A copy of this notice **MUST** be returned with the reply.*

AT
Customer Service Center

Initial Patent Examination Division (703) 308-1202

PART 2 - COPY TO BE RETURNED WITH RESPONSE

12/26/2001 WBERHE 00000051 09884526

01 FC0105

130.00 OP



UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
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| APPLICATION NUMBER | FILING DATE | GRP ART UNIT | FIL FEE REC'D | ATTY. DOCKET NO | DRAWINGS | TOT CLAIMS | IND CLAIMS |
|--------------------|------------------|--------------|---------------|-----------------|----------|------------|------------|
| 09/884,526 | 06/20/2001 19 | 3763 | 710 | 4274-4000 | 2 | 11 | 1 |

CONFIRMATION NO. 2532

FILING RECEIPT



OC00000006418069

MORGAN & FINNEGAN, L.L.P.
345 Park Avenue
New York, NY 10154-0053



Date Mailed: 08/13/2001

Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Customer Service Center. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

David Meeker, Paris, FRANCE;
Seng H. Cheng, Wellesley, MA;

Domestic Priority data as claimed by applicant

THIS APPLN CLAIMS BENEFIT OF 60/212,377 06/19/2000

Foreign Applications

If Required, Foreign Filing License Granted 08/13/2001

Projected Publication Date: To Be Determined - pending completion of Missing Parts

Non-Publication Request: No

Early Publication Request: No

Title

Combination enzyme replacement, gene therapy and small molecule therapy for lysosomal storage diseases

Preliminary Class

604

CASE 4274-4000 ATTY KHS
INFORMATION DISCLOSURE
STATEMENT
FOREIGN FILING
CONVENTION DATE EXPIRES
September 20, 2001
March 20, 2002
June 20, 2002

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AUG 17 2001

MORGAN & FINNEGAN L.L.P.

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Data entry by : TESFAYE, ALEM

Team : OIPE

Date: 08/13/2001

**LICENSE FOR FOREIGN FILING UNDER
Title 35, United States Code, Section 184
Title 37, Code of Federal Regulations, 5.11 & 5.15**

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Office of Export Administration, Department of Commerce (15 CFR 370.10 (j)); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

PLEASE NOTE the following information about the Filing Receipt:

- The articles such as "a," "an" and "the" are not included as the first words in the title of an application. They are considered to be unnecessary to the understanding of the title.
- The words "new," "improved," "improvements in" or "relating to" are not included as first words in the title of an application because a patent application, by nature, is a new idea or improvement.
- The title may be truncated if it consists of more than 500 characters (letters and spaces combined).
- The docket number allows a maximum of 25 characters.
- If your application was submitted under 37 CFR 1.10, your filing date should be the "date in" found on the Express Mail label. If there is a discrepancy, you should submit a request for a corrected Filing Receipt along with a copy of the Express Mail label showing the "date in."
- The title is recorded in sentence case.

Any corrections that may need to be done to your Filing Receipt should be directed to:

Assistant Commissioner for Patents
Office of Initial Patent Examination
Customer Service Center
Washington, DC 20231



KHS/sc

APPLICATION TRANSMITTAL RETURN RECEIPT CARD

Receipt is acknowledged of the following patent application:

APPLICANT(s): DAVID MEEKER, ET AL.

TITLE: COMBINATION ENZYME REPLACEMENT, GENE THERAPY AND SMALL MOLECULE THERAPY FOR LYSOSOMAL STORAGE DISEASES

PAGES: (40) **CLAIMS:** (2) **DRAWINGS:** (2) ^{Formal} sheets

DECLARATION ☒ * **OATH** ☐

FEE: () **CHECK** ☐ **CHARGED TO DEP.ACC. 13-4500** ☒

*unexecuted

~~J1036 U.S. PTO~~

~~09/884526~~



~~06/20/01~~

4274-4000

SERIAL NO. _____

Express Mail Label No. EL 762623628

J1036 U.S. PTO

09/884526



06/19/01

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DEPUTY A/C PATENTS**



Docket No. 4274-4000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): DAVID MEEKER, ET AL.

Group Art Unit: To Be As signed

Serial No.: To be Assigned

Examiner: To be Assigned

Filed: June 19, 2001

For: COMBINATION ENZYME REPLACEMENT, GENE THERAPY AND SMALL MOLECULE THERAPY FOR LYSOSOMAL STORAGE DISEASES

EXPRESS MAIL CERTIFICATE

Express Mail Label No.: E1 762623628US

Date of Deposit: June 19, 2001


I hereby certify that the following attached paper(s) and/or fee

1. UTILITY APPLICATION AND FEE TRANSMITTAL §(1.53(B))
(4 pages – in duplicate)
2. SPECIFICATION (40 pages); ABSTRACT (1 page); CLAIMS
(2 pages)
3. FORMAL DRAWINGS - FIGURES 1A-1B (2 Sheets)
4. COMBINED DECLARATION AND POWER OF ATTORNEY
(6 pages - Unexecuted)
5. RETURN RECEIPT POSTCARD

are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. §1.10 on the date indicated above and is addressed to the Commissioner for Patents, Washington, D.C. 20231.

Kenneth H. Sonnenfeld

(Typed or printed name of person mailing paper(s) and/or fee)


(Signature of person mailing paper(s) and/or fee)

Correspondence Address:

MORGAN & FINNEGAN, L.L.P.
345 Park Avenue
New York, NY 10154-0053
(212) 758-4800 Telephone
(212) 751-6849 Facsimile

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27123

PATENT TRADEMARK OFFICE

Docket No. 4274-4000

Express Mail No. EL762623628US

↑ AFFIX CUSTOMER NO. LABEL

↑
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**UTILITY APPLICATION AND FEE TRANSMITTAL \$(1.53(b))**

Commissioner for Patents
BOX PATENT APPLICATION
Washington, D.C. 20231

Sir:

Transmitted herewith for filing is the patent application of

Inventor(s) names and addresses:

- (1) David Meeker
93 rue Jouffroy
Paris 75017 France
- (2) Seng H. Cheng
50 Wall Street
Wellesley, Massachusetts 02481

☐ Additional inventors are listed on a separate sheet

For: COMBINATION ENZYME REPLACEMENT, GENE THERAPY AND SMALL
MOLECULE THERAPY FOR LYSOSOMAL STORAGE DISEASES

Enclosed Are:

- 40 page(s) of specification
1 page(s) of Abstract
2 page(s) of claims
2 sheets of ☒ Formal ☐ Informal drawings
6 page(s) of Declaration and Power of Attorney

- ☒ Unsigned
☐ Newly Executed
☐ Copy from prior application
☐ Deletion of inventors including Signed Statement under 37 C.F.R. §1.63(d)(2)

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DEPUTY A/C PATENTS

☐ **REQUEST AND CERTIFICATION UNDER 35 U.S.C. §122(b)(2)(B)(i) (form PTO/SB/35)**

As indicated on the attached Request and Certification, Applicant(s) certify that the invention disclosed in the attached application HAS NOT and WILL NOT be the subject of an application filed in another country, or under a multilateral agreement, that requires publication at eighteen months after filing. Applicant(s) therefore request(s) that the attached application NOT be published under 35 U.S.C. §122(b).

☒ **Incorporation by Reference:**

☒ The entire disclosure of the prior provisional application, Serial No. 60/212,377 filed June 19, 2000, is considered as being part of the disclosure of the accompanying application and is incorporated herein by reference.

☐ **Deletion of Inventors (37 C.F.R. §1.63(d) and §1.33(b))**

Signed statement attached deleting inventor(s) named in the prior application serial no. _____, filed _____.

☐ **Microfiche Computer Program (Appendix)**

- ☐ page(s) of Sequence Listing
- ☐ computer readable disk containing Sequence Listing
- ☐ Statement under 37 C.F.R. §1.821(f) that computer and paper copies of the Sequence Listing are the same

☒ **Assignment Papers (assignment cover sheet and assignment documents)**

- ☐ A check in the amount of \$40.00 for recording the Assignment
- ☐ Charge the Assignment Recordation Fee to Deposit Account No. 13-4500, Order No. _____.
- ☒ Assignment Papers filed in the provisional application Serial No. 60/212,377

☐ **Certification of chain of title pursuant to 37 C.F.R. §3.73(b)**

☐ **Priority is claimed under 35 U.S.C. §119 for:**
Application No(s). __, filed __, in __ (country).

☐ **Certified Copy of Priority Document(s) [_____]**

- ☐ filed herewith
- ☐ filed in application Serial No. _____, filed _____.

☐ **English translation document(s) [_____]**

- ☐ filed herewith
- ☐ filed in application Serial No. _____, filed _____.

☒ **Priority is claimed under 35 U.S.C. §119(e) for:**
Provisional Application No. 60/212,377, filed June 19, 2000.

- ☐ Information Disclosure Statement
- ☐ Copy of [] cited references
- ☐ PTO Form-1449
- ☐ References cited in parent application Serial No. _____, filed _____.
- ☐ Related Case Statement under 37 C.F.R. §1.98(a)(2)(iii)
- ☐ A copy of related pending U.S. Application(s) Serial No(s): _____, filed _____, respectively, is attached hereto.
- ☐ A copy of related pending U.S. Application(s) entitled, _____, filed _____ to inventor(s) _____, respectively, is attached hereto.
- ☐ A copy of each related application(s) was submitted in parent application serial no. _____, filed _____.
- ☐ Preliminary Amendment
- ☒ Return receipt postcard (MPEP 503)
- ☐ This is a ☐ continuation ☐ divisional ☐ continuation-in-part of prior application serial no. _____, filed _____, to which priority under 35 U.S.C. §120 is claimed.
- ☐ Cancel in this application original claims _____ of the parent application before calculating the filing fee. (At least one original independent claim must be retained for filing purposes.)
- ☐ A Preliminary Amendment is enclosed. (Claims added by this Amendment have been properly numbered consecutively beginning with the number following the highest numbered original claim in the prior application).
- ☐ The status of the parent application is as follows:
- ☐ A Petition for Extension of Time and a Fee therefor has been or is being filed in the parent application to extend the term for action in the parent application until _____.
- ☐ A copy of the Petition for Extension of Time in the co-pending parent application is attached.
- ☐ No Petition for Extension of Time and Fee therefor are necessary in the co-pending parent application.
- ☐ Please abandon the parent application at a time while the parent application is pending or at a time when the petition for extension of time in that application is granted and while this application is pending has been granted a filing date, so as to make this application co-pending.
- ☐ Transfer the drawing(s) from the parent application to this application
- ☐ Amend the specification by inserting before the first line the sentence:
This is a ☐ continuation ☐ divisional ☐ continuation-in-part of co-pending application Serial No. _____, filed _____.

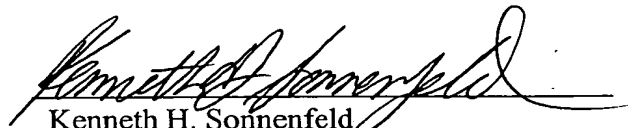
| I. CALCULATION OF APPLICATION FEE | | | | |
|--|--------------|---|------------------|------------------------------|
| | Number Filed | Number Extra | Rate | Basic Fee \$710.00/355.00 |
| Total Claims | 11- 20 = | 0x | \$18.00/ \$9.00 | \$ 0 |
| Independent Claims | 1- 3 = | 0x | \$80.00/ \$40.00 | \$ 0 |
| <input type="checkbox"/> Multiple Dependent Claims | | If marked, add fee of \$270.00 (\$135.00) | | \$ 0 |
| TOTAL: | | | | \$ 710.00 |

- ☐ Small entity status is or has been claimed. Reduced fees under 37 C.F.R. §1.9 (f) paid herewith \$_____.
- ☐ A check in the amount of \$_____ in payment of the application filing fees is attached.
- ☒ Charge fee to Deposit Account No. 13-4500, Order No. 4274-4000. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.
- ☒ The Commissioner is hereby authorized to charge any additional fees which may be required for filing this application pursuant to 37 CFR §1.16, **including all extension of time fees pursuant to 37 C.F.R. § 1.17 for maintaining copendency** with the parent application, or credit any overpayment to Deposit Account No. 13-4500, Order No. 4274-4000. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,
MORGAN & FINNEGAN, L.L.P.

Dated: June 19, 2001

By:


Kenneth H. Sonnenfeld
Registration No. 33,285

Correspondence Address:

MORGAN & FINNEGAN, L.L.P.
345 Park Avenue
New York, NY 10154-0053
(212) 758-4800 Telephone
(212) 751-6849 Facsimile



27123

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Docket No. 4274-4000

10

UNITED STATES PATENT APPLICATION

15

FOR

20

COMBINATION ENZYME REPLACEMENT, GENE THERAPY
AND SMALL MOLECULE THERAPY FOR
LYSOSOMAL STORAGE DISEASES

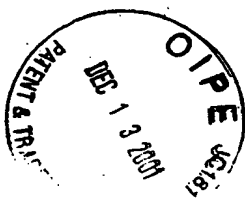
25

BY

DAVID MEEKER AND SENG H. CHENG

30

35



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NEW YORK, NY 10022-9998
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ck Unit Id SIADAVID
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Total Cost: 16.00
Base Rate: 16.00
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Subtotal 0.00
Total 0.00

Number of Items Sold: 2

Thank You

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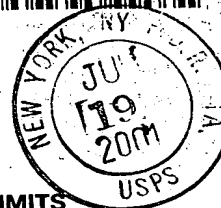
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NEW YORK NY 10154-0053

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4274-4000

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Case No. 4274-4000PC Serial No. TBA
Date Mailed 19 June 01 ATTY KHS
Date Due in the Patent Office 19 June 01

The return of this post card, properly stamped, will
acknowledge receipt in the Patent & Trademark Office
of the following:

PCT/US 01/19579

1. - PCT International Application Transmittal Letter to the United
2. - States Receiving Office (RO/US), with certification under 37 CFR
3. - 1.10, duly executed; ~~Verified Certification of Express Mail~~
~~El 762623407US~~ PCT Request Form RO/101 (5 sheets), duly
4. - executed; Fee Calculation Sheet (in duplicate); International
5. - Application, with 40 pages of description, 2 pages of claims; 1 page
6. - of Abstract and 2 sheets of drawings (Figs 1A-1B; and Return
6. - Postcard.

JC17 Rec'd PCT/PTO 19 JUN 2001

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**OFFICE OF PETITIONS
DEPUTY A/C PATENTS**

PATENT COOPERATION TREATY

From the RECEIVING OFFICE

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NOTIFICATION OF THE INTERNATIONAL APPLICATION NUMBER AND OF THE INTERNATIONAL FILING DATE

(PCT Rule 20.5(c))

To:

KENNETH H. SONNENFELD
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345 PARK AVENUE
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Date of mailing
(day/month/year)

20 JUL 2001

Applicant's or agent's file reference

4274-4000PC

IMPORTANT NOTIFICATION

International application No.

PCT/US01/19579

International filing date (day/month/year)

19 JUN 01

Priority date (day/month/year)

19-JUN 00

Applicant

GENZYME CORPORATION

Title of the invention

COMBINATION ENZYME REPLACEMENT, GENE THERAPY AND
SMALL MOLECULE THERAPY FOR LYSOSOMAL STORAGE

1. The applicant is hereby notified that the international application has been accorded the international application number and the international filing date indicated above.

2. The applicant is further notified that the record copy of the international application: **20 JUL 2001**



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37 CFR 5.15(a)



37 CFR 5.15(b)

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